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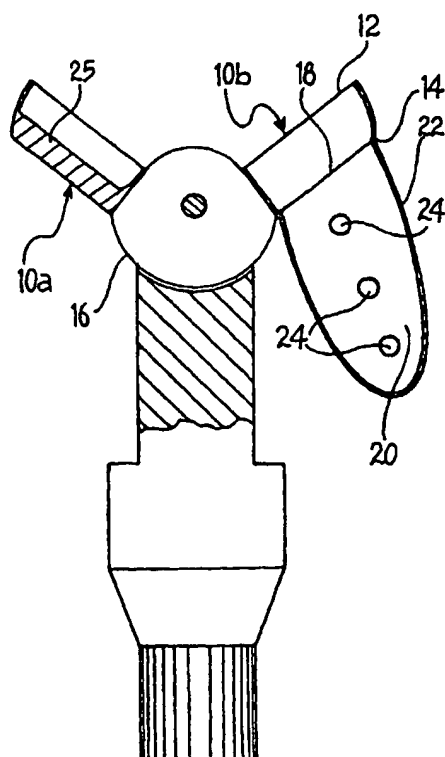
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **FORCEPS FOR MEDICAL USE**



(57) Abstract: The forceps comprises two half-shells (10a, 10b) each of which has a front rim (12) and a base wall (14) and which are mounted on a support element (16) in a manner such that they can adopt a first, opened-out configuration and a second, closed configuration. The forceps has at least one container element (22) having a cavity (20) for receiving a plurality of biopsy samples. The container element (22) is preferably associated with one (10b) of the half-shells (10a, 10b).

WO 01/30242 A1

Forceps for medical use

The present invention relates to forceps for medical use, in particular for biopsy, for example, for endoscopic biopsy, laparoscopy, gynaecological applications and the like.

More specifically, a conventional forceps of this type comprises two half-shells, each of which has a front rim and a base wall, and which are mounted on a support element in a manner such that they can adopt a first, opened-out configuration and a second, closed configuration.

In use, for example, during digestive endoscopy, the forceps is passed through the operating duct of an endoscope in the closed configuration and is brought into contact with the internal mucosa of the organ (for example, the oesophagus, stomach, duodenum, or colon) to be biopsied.

Once the forceps has been positioned correctly, the half-shells are opened and then closed so as to cut off a sample of the mucosa which remains held between them. Given the intrinsically limited nature of the space available, the closed half-shells can hold at most 2-3 biopsy samples.

However, pathological conditions frequently occur in which the number of samples taken has to be greater, as with gastric ulcers, or dysplasia or neoplasia in ulcerative pancolitis, which is a serious chronic disease of the colon.

In these cases, each time the space inside the half-shells is filled with biopsy samples, the forceps has to be withdrawn through the endoscope duct, emptied and reintroduced to the operation site. A large amount of wear and deformation of the duct thus takes place, with the risk

of rupture and consequent infiltration of liquid which may cause very serious damage to the endoscope.

Another problem connected with the need to perform a plurality of introductions and withdrawals of the forceps consists of the long duration of this procedure which is due, amongst other things, to the need to empty the half-shells. Owing to the small size of the samples taken, this operation in fact takes the operator a considerable amount of time. In operative practice, however, the time available - in certain conditions, for example, with markedly intolerant patients who are unable to take sedatives - may be very limited, so that the use of conventional forceps is difficult.

To prevent the problems of the prior art mentioned above, the subject of the present invention is forceps of the type described at the beginning of the present description and characterized in that it has at least one container element having a cavity for receiving a plurality of biopsy samples.

The forceps of the invention can therefore be used to take all of samples necessary for a given pathological condition, in succession, by performing only one introduction and withdrawal, thus considerably reducing the time required for the operation, as well as the wear of the endoscope duct.

Moreover, during the withdrawal stage, the container element keeps the biopsy samples isolated from the duct, which has the advantage of preventing any mixing with impurities or with any scraps remaining from other samples taken, which may be present therein.

Further advantages and characteristics of the present invention will become clear from the following detailed

description, provided by way of non-limiting example with reference to the appended drawings, in which:

Figure 1 is a schematic plan view of a forceps of the invention,

Figure 2 is a front elevational view of the forceps of Figure 1,

Figure 3 is a section view taken on the line III-III of Figure 1,

Figures 4 and 5 are respective plan views of each of the two half-shells of a forceps constituting an alternative embodiment of the invention,

Figure 6 is a section taken on the line VI-VI of Figure 4,

Figure 7 is a section view taken on the line VII-VII of Figure 5, and

Figures 8 and 9 are views corresponding to Figures 5 and 7, respectively, of a further embodiment of a detail of a forceps of the invention.

A biopsy forceps, for example, for endoscopic biopsy, comprises (Figures 1-3) two half-shells 10a, 10b each having a front rim 12 and a base wall 14. The half-shells 10a, 10b are mounted in conventional manner, for example, on a support element 16 so that they can adopt a first, opened-out configuration (shown in the drawings) and a second, closed configuration in which the rims 12 of the two half-shells 10a, 10b are in contact with one another.

The half-shell 10b has, in its base wall 14, a hole 18 which communicates with the cavity 20 inside a beaker-shaped container element 22 associated therewith and having a plurality of through-openings 24 in its walls.

The material constituting the element 22 is not critical within the scope of the present invention and may be selected, without particular limitations, from those suitable for use in the medical field.

The half-shell 10a, on the other hand, is filled up to approximately a third of its height with filling material 25.

In use, the forceps is first of all passed through an endoscope duct (not shown in the drawings), with the half-shells 10a, 10b in the closed configuration, until the forceps is in the desired location close to the internal mucosa of the organ to be biopsied. Here, the half-shells 10a, 10b are opened out and closed again several times in succession so as to cut off a corresponding number of biopsy samples.

As these samples are taken one by one, they are urged towards the base of the container element 22 by the pressure exerted by the half-shell 10a.

The openings 24 allow air and any organic liquids which remain trapped in the cavity 20 of the element 22 to be discharged, further facilitating the movement of the biopsy samples inside the element 22.

Upon completion of the cutting of the samples, the half-shells 10a, 10b are closed again and the forceps, with its container element 22, can be withdrawn through the endoscope

duct. The biopsy samples which are enclosed inside the cavity 20 do not therefore have any substantial contact with the duct, which could constitute a potential source of histological contamination.

Figures 4 to 7 show an alternative embodiment of the half-shells of a biopsy forceps according to the invention, which half-shells can be mounted on a support element in a manner similar to that described with reference to Figures 1-3.

In this embodiment, the half-shell 10a with which the container element 20 is not associated has (Figures 4 and 6) a base wall 14 having a central portion 26 which is raised substantially to the level of the rim 12, and an annular, recessed, peripheral portion 28.

The half-shell 10b, on the other hand, (Figures 5 and 7) has, in its base wall 14, the hole 18 in which the end of the beaker-shaped container element 22 is fixed by means of an annular layer of adhesive 30, this end being open and having a restricted neck. The internal cavity 20 of the container element 22 thus constitutes a continuation of the space inside the half-shell 10b.

The container element 22 also has openings 24 in its base and side walls.

The principle of the operation of the forceps having the half-shells just mentioned is substantially similar to that described with reference to Figures 1-3. The particular shape of the half-shell 10a enables a greater pressure to be exerted on the biopsy samples, directing them towards the cavity 20 of the element 22.

Figures 8 and 9 show a variant of the fixing of the container element 22 to the half-shell 10b, which is an alternative to the use of the above-described layer of adhesive. In this case, the open end of the element 22 has a hooked rim for engaging a rim of complementary shape of the hole 18 of the half-shell 10b. This engagement is preferably secured by a mechanical element such as a spring ring 32.

Naturally, the principle of the invention remaining the same, the details of construction and forms of embodiment may be varied widely with respect to those described purely by way of example, without thereby departing from its scope. In particular, both of the half-shells may have their own container elements and/or may have, independently of one another, any shape, for example, with a toothed or serrated rim. The container element in turn may have substantially any shape and/or length and/or may be in the form of a net engaged directly on the rim of the associated half-shell. Moreover, the container element may equally well be secured on the respective half-shell immovably, or releasably.

CLAIMS

1. Forceps for medical use, in particular for biopsy, comprising two half-shells (10a, 10b) each of which has a front rim (12) and a base wall (14) and which are mounted on a support element (16) in a manner such that they can adopt a first, opened-out configuration and a second, closed configuration,

the forceps being characterized in that it has at least one container element (22) having a cavity (20) for receiving a plurality of biopsy samples.

2. Forceps according to Claim 1, characterized in that the container element (22) is associated with at least one (10b) of the half-shells (10a, 10b).

3. Forceps according to any one of the preceding claims, characterized in that a half-shell (10a) with which the container element (22) is not associated has a base wall (14) having a central portion (26) which is raised substantially to the level of the rim (12), and an annular, recessed, peripheral portion (28).

4. Forceps according to any one of the preceding claims, characterized in that at least one (10b) of the half-shells (10a, 10b) has, in its base wall (14), a hole (18) which communicates with the cavity (20) of the container element (22) associated with the said half-shell (10b).

5. Forceps according to Claim 4, characterized in that the open end of a beaker-shaped container element (22) is fixed in the hole (18) in a manner such that its internal cavity (20) constitutes a continuation of the space inside the half-shell (10b).

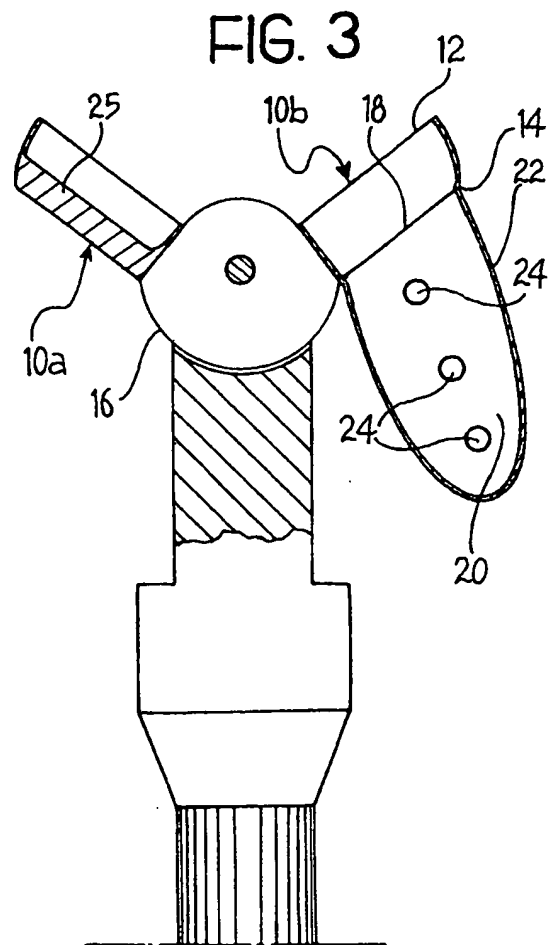
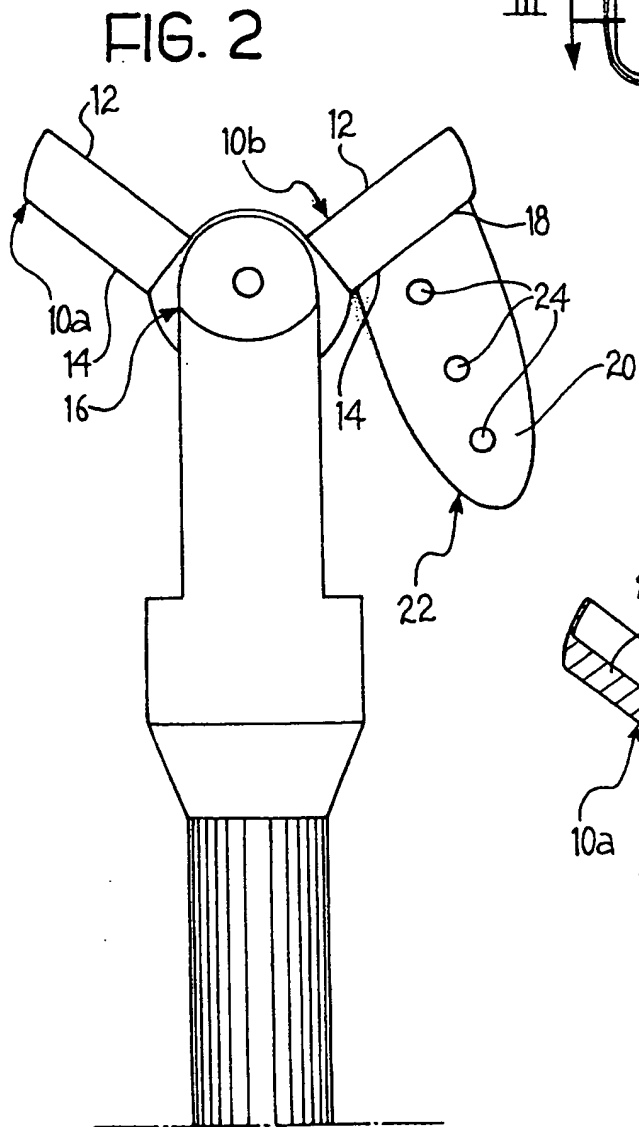
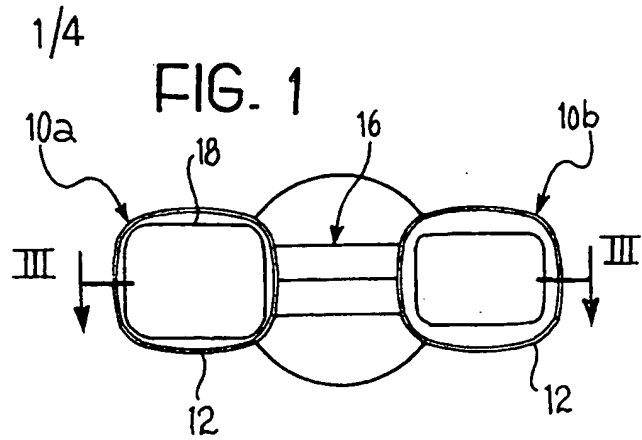
6. Forceps according to Claim 5, characterized in that the open end is fixed to the half-shell (10b) by means of an annular layer of adhesive (30).

7. Forceps according to Claim 5, characterized in that the open end has a hooked rim for engaging a rim of complementary shape of the hole (18) of the half-shell (10b).

8. Forceps according to Claim 7, characterized in that the engagement of the rim of the open end of the container element (22) with the rim of the hole (18) of the half-shell (10b) is secured by a mechanical element such as a spring ring (32).

9. Forceps according to any one of the preceding claims, characterized in that the container element (22) is beaker-shaped and has at least one opening (24) in its base and/or in its side walls.

10. Forceps according to Claim 9, characterized in that the container element (22) has a plurality of openings (24) in its base and in its side walls.



2/4

FIG. 4

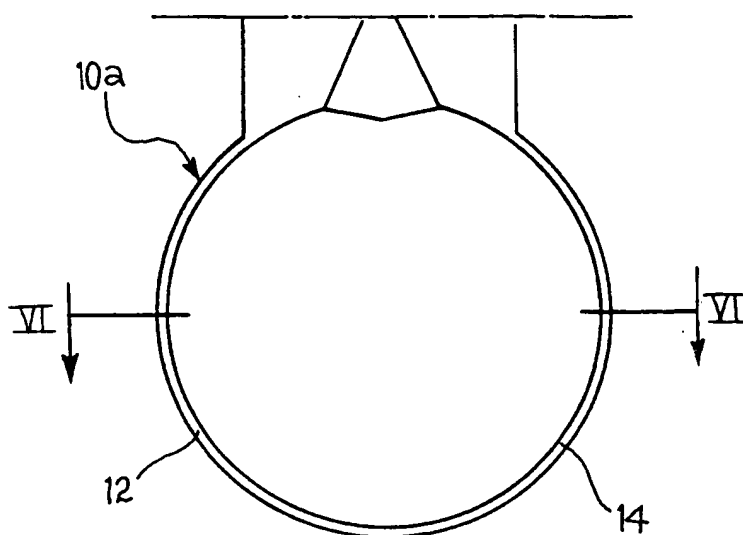
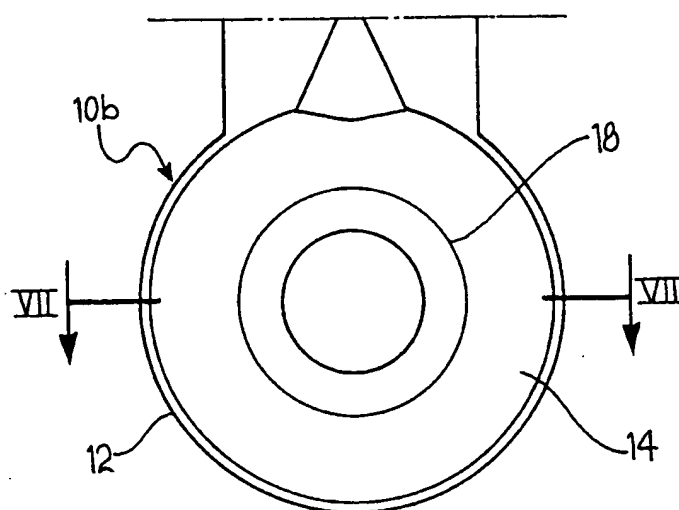


FIG. 5



3/4

FIG. 6

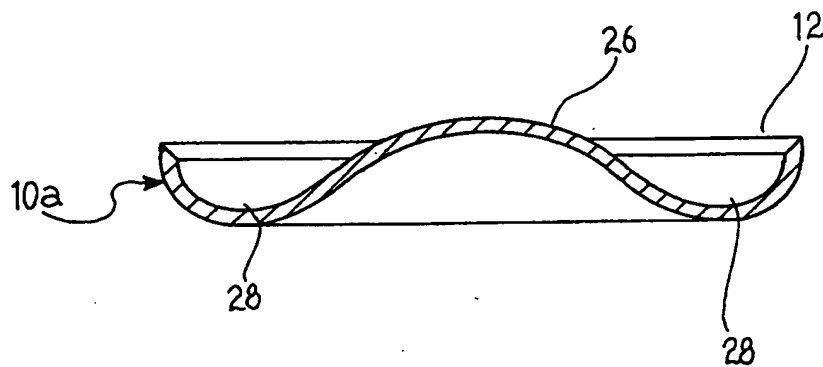
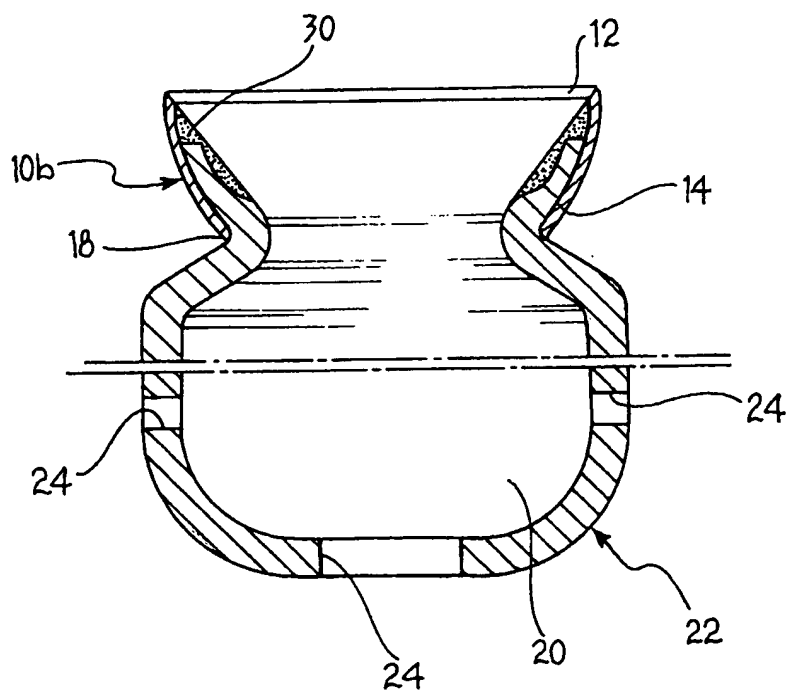


FIG. 7



4/4

FIG. 8

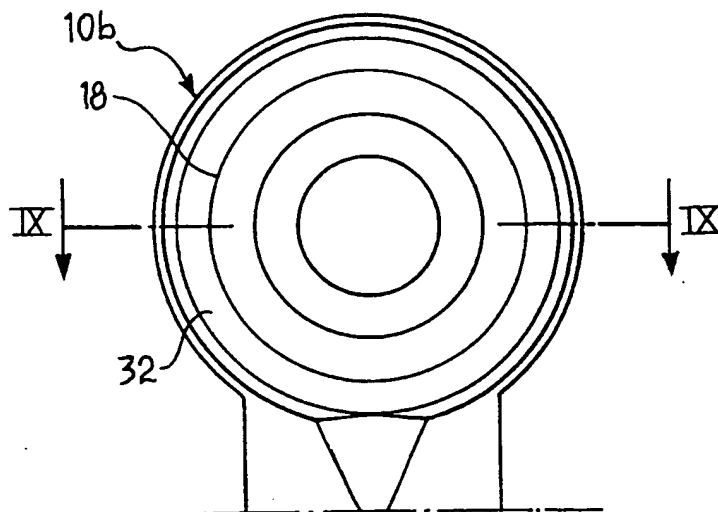
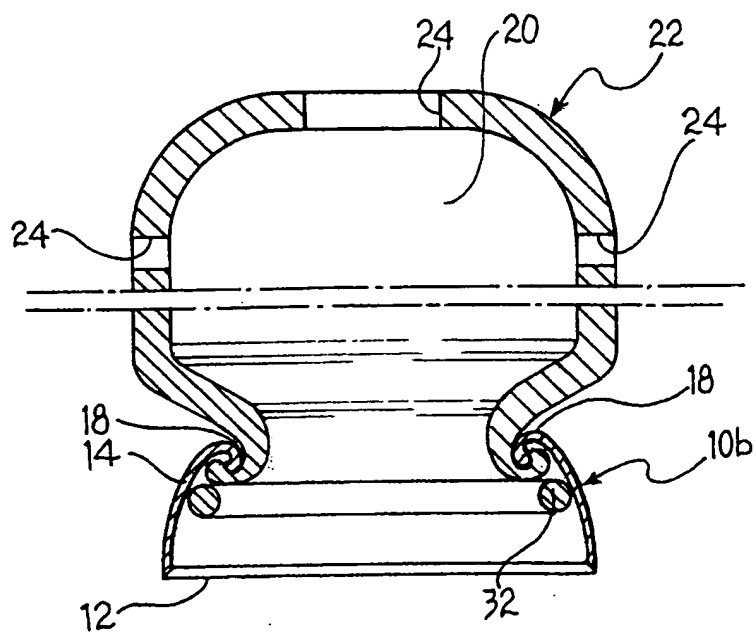


FIG. 9



INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 643 307 A (KORTENBACH JUERGEN ANDREW ET AL) 1 July 1997 (1997-07-01) column 3, line 33 -column 4, line 43; figures 1-5	1-4,9,10
X	US 5 951 488 A (MCBRAYER MICHAEL SEAN ET AL) 14 September 1999 (1999-09-14) claims 1,4; figure 5	1,2
X	US 5 662 671 A (PASTRONE GIOVANNI ET AL) 2 September 1997 (1997-09-02) column 16, line 8 - line 21; figure 16	1,2,4-10
A	US 1 609 014 A (DOWD) 30 November 1926 (1926-11-30) figures 1,2	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5643307 A	01-07-1997	US 5893876 A	13-04-1999
US 5951488 A	14-09-1999	US 5647115 A	15-07-1997
		US 5542432 A	06-08-1996
		US 5507296 A	16-04-1996
		AU 694757 B	30-07-1998
		AU 1568695 A	21-08-1995
		CA 2181545 A	10-08-1995
		CN 1143899 A	26-02-1997
		EP 0843533 A	27-05-1998
		JP 9508540 T	02-09-1997
		WO 9520914 A	10-08-1995
		US 5636639 A	10-06-1997
		US 5638827 A	17-06-1997
		US 5645075 A	08-07-1997
		US 5746216 A	05-05-1998
		US 5840043 A	24-11-1998
		US 5431645 A	11-07-1995
		US 5395386 A	07-03-1995
		US 5482054 A	09-01-1996
		US 5613499 A	25-03-1997
		US 5666965 A	16-09-1997
		US 5228451 A	20-07-1993
		US 6024708 A	15-02-2000
		US 5241968 A	07-09-1993
US 5662671 A	02-09-1997	AU 3888097 A	09-02-1998
		EP 0930842 A	28-07-1999
		US 5997557 A	07-12-1999
		WO 9802084 A	22-01-1998
		US 6010522 A	04-01-2000
		US 5895399 A	20-04-1999
		US 5993469 A	30-11-1999
US 1609014 A	30-11-1926	NONE	